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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,878	11/30/2001	Richard E. Fulton III	216226US-25 CONT	4138

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/996,878	FULTON ET AL.
	Examiner	Art Unit
	Brian Szmal	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-67,69-72,75,76,80 and 83-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-67,69-72,75,76,80 and 83-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 53-67, 69-72, 75, 76, 80 and 83-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a palpable bioabsorbable marker element that can also be imaged by radiographic or ultrasonic means, does not reasonably provide enablement for dictating the amount of time the bioabsorbable element remains at the site, coloring the marker, and the marker uses a dry powder, sponge or a liquid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification of the current invention enables a palpable bioabsorbable marker element that is placed at the site of a biopsy in order to allow the surgeon to more easily relocate the biopsy site. The relocation can be performed through the use of palpation, or through the use of imaging through radiographic and ultrasonic means. The specification also states the marker is made from polylactic acid, polyglycolic acid, lipids, gelatin, hydrogels and other gels, and preferably dehydrated collagen. The specification also fails to disclose a marker comprising, a sponge, a liquid, collagenous material with radiographically imageable material attached to the marker, and the material comprising ions. The specification also enables the marker including a radiopaque marker. See Page 6, lines 23-27; Page 8, lines 24-26; and Page 9, lines 4-

8. However, only the summary supports the marker being visually detectable through the use of dyes or coloring agents. See Page 4, lines 28-29. Furthermore, the use of carbon is only disclosed in the Background of the Invention (See Page 2, lines 16-18), and further discloses the problem of using carbon, and the current invention overcomes the problems of these previous or current means for localization of a site. The specification also fails to disclose the use a visualization means for the marker element, including a coloring means using dyes and carbon.

The specification fails to explicitly disclose the time frame in which the bioabsorbable marker is fully resorbed by the body, for instance the "predetermined time" as claimed in Claims 53, 54, 61 and 62. It is well known in the art that a bioabsorbable element will dissipate at the site over time, but the specification does not disclose: staying at the site for a predetermined amount of time to permit the relocation of the biopsy site; the marker does not interfere with the imaging of the surrounding tissue after a set time; the marker interferes with the imaging of the surrounding tissue during a first time but not after a second time point; and more specifically a time frame of "2 weeks" as stated in Claim 62, a time frame in which the marker would be resorbed by the body and imaging of the surrounding tissues would not be affected. The specification also fails to disclose the use of a clearance-delaying element using an encapsulating material to delay the decomposition of the bioabsorbable element.

Claim Objections

3. Claim 76 is objected to because of the following informalities: The claim refers to cancelled Claim 74 in line 1 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 53-61, 65-67, 72, 80 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al ('055) in view of Stinson ('564).

Foerster et al disclose a device of marking and defining particular locations in body tissue, and further disclose introducing into the site a detectable marker that remains at the site for a predetermined time; does not interfere with imaging the site at a second time; the marker is detected by using radiographic imaging techniques; the marker is detectable by palpation; the marker comprises at least one pellet; the marker is visually detectable using a dye or a coloring agent; the marker is detectable by using imaging, palpation or visualization; the marker comprises material that is detectable by radiographic, sonographic or magnetic imaging means. See Column 1, lines 19-23; Column 3, lines 26-33; Column 7, lines 24-26 and 41-65; Column 8, lines 62-67; Column 9, lines 1-4; and Column 13, lines 19-26 and 33-36.

Foerster et al discloses in Column 13, lines 33-36, that biodegradable polymers could also be used, but does not explicitly disclose the polymer lasting at the site for a

predetermined time to permit detection of the marker, and not interfering with imaging after the polymer has been reabsorbed. Foerster et al also fails to explicitly disclose radiographically imageable matter placed on the implant, but does disclose the implant being visible using an imaging system.

Stinson discloses the use of a bioabsorbable implantable device and further discloses the bioabsorbable/biodegradable polymer lasting at the site for predetermined periods of time, depending upon the composition of the implant, and is eliminated from the site after a period of time. (See Column 2, lines 43-48) Since the implant is eliminated from the site, the implant will not interfere with imaging the site once the implant has been fully reabsorbed. Stinson also discloses the use of radiographically imageable material on the implant to provide a detectable marker. See Column 3, lines 50-52; and Column 23, lines 43-48.

Since both Foerster et al and Stinson disclose bioabsorbable materials for implantation, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the disclosure of the type of polymer and the time of degradation of the bioabsorbable polymer, as per the teachings of Stinson, since it would provide an explicit disclosure of the bioabsorbable implant.

6. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al ('055) and Stinson ('564) as applied to claim 53 above, and further in view of Unger et al ('834).

Foerster et al, as discussed above, disclose a bioabsorbable marker that is placed at a biopsy site, but fail to disclose a detectable material that is encapsulated in a clearance

delaying material; the detectable material is a lipid; and the clearance delaying material is polylactic or polyglycolic acid.

Unger et al disclose methods for ultrasound imaging involving the use of a contrast agent and further disclose a detectable material that is encapsulated in a clearance delaying material; the detectable material is a lipid; and the clearance delaying material is polylactic or polyglycolic acid. See Column 6, lines 62-67; Column 7, lines 1-4 and 7-38; Column 21, lines 63-67; Column 22, lines 1-3 and line 40 and lines 47-48; Column 73, lines 35-40.

Since Foerster et al, Stinson and Unger et al disclose the use of a biodegradable marker, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Foerster et al and Stinson to include a lipid filled degradable marker, as per the teachings of Unger et al, since it would provide another means for utilizing CT or MRI as an imaging means to locate the biopsy site.

8. Claims 75, 76, 83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al ('055) and Stinson ('564) as applied to claim 53 above, and further in view of Ragheb et al ('904).

Foerster et al and Stinson, as discussed above, disclose a bioabsorbable marker that is placed at a biopsy site, but fail to disclose the radiologically imageable matter includes ions; the imageable matter comprises a marker; and the marker comprises gelatinous material having radiologically imageable matter combined therewith.

Ragheb et al disclose a silver implantable medical device and further disclose the use of a collagenous material having radiologically imageable matter attached thereto; the

radiologically imageable matter includes ions; the imageable matter comprises a marker; and the marker comprises gelatinous material having radiologically imageable matter combined therewith. See Column 9, lines 1-25.

Since Foerster et al, Stinson and Ragheb et al disclose bioabsorbable imageable devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Foerster et al and Stinson to include the use of a collagenous material as the base and a coating of a radiopaque substance, as per the teachings of Ragheb et al, since a coating on a collagenous material, well known in the art that as a bioabsorbable material, would provide a means of relocating the implant at the site using radiographic means at a later time. It also would have been obvious to one of ordinary skill in the art to utilize gelatin, since it is well known that gelatin is derived from collagen.

7. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al ('055) and Stinson ('564) as applied to claim 53 above, and further in view of Park et al ('278).

Foerster et al and Stinson, as discussed above, disclose means for a bioabsorbable implant, but fail to disclose the marker comprising a sponge.

Park et al disclose a superporous hydrogel composite that acts like a sponge and has a marker placed inside to provide a means of remotely visualizing the position of the hydrogel/marker in the body. See Column 31, lines 5-9 and 23-26.

Since Foerster et al, Stinson and Park et al disclose bioabsorbable material for marking a position in tissue, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to modify the combination of Foerster et al and Stinson to include the use of a sponge-like material as a marker, as per the teachings of Park et al, since a sponge-like material is an obvious variant of a marker that can include solid, semi-solid, semi-porous, liquid or a gel.

8. Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al ('055) and Stinson ('564) as applied to claim 53 above, and further in view of Ersek et al ('182).

Foerster et al and Stinson, as discussed above, disclose means for a bioabsorbable implant, but fail to disclose the use of a liquid or a flowable material placed into tissue. Ersek et al discloses the use of textured micro-implants and further disclose the use of a liquid or a flowable material, in particular collagen, placed into tissue. See Column 7, lines 56-68.

Since Foerster et al, Stinson and Ersek et al disclose the placement of bioabsorbable materials into tissue, it would have been obvious to one of ordinary skill in the art to modify the combination of Foerster et al and Stinson to include the use of a flowable or liquid collagen injection a the tissue site, as per the teachings of Ersek et al, since a flowable material is merely a variant of a marker that can include solid, semi-solid, or semi-porous.

Response to Arguments

9. Applicant's arguments filed March 1, 2004 have been fully considered but they are not persuasive. With respect to the 112 rejections above and the response

submitted on March 1, 2004, the Examiner traverses the arguments that the currently claimed material is sufficiently supported by the current specification because of the prior disclosure in the provisional applications. The above subject matter, in particular, the time period of "2 weeks" in Claim 62, the use of an encapsulating material in Claim 64, the use of a sponge in Claim 69, a liquid in Claim 70, ions coating the material in Claims 75 and 83, and collagenous material in Claim 57, is not disclosed nor is it enabled by the current specification. The argument that a provisional application to which the current application claims priority to constitutes a sufficient disclosure to provide enablement for the claimed subject matter is not correct. The claimed subject matter must be in the current specification to provide proper enablement for the claimed subject matter.

The Examiner also traverses the argument that the use of a sponge is disclosed by the current specification and the provisional applications. The material disclosed in the current specification and the provisional applications disclose a swellable material for introduction at a biopsy site. A sponge does not swell when it comes into contact with a fluid; it soaks the fluid up. If a sponge did swell when it would come into contact with a fluid, then a car wash sponge would swell when it would come into contact with water and shrink when the water would be removed. The claimed material swells because it is a dehydrated material and when it comes into contact with a fluid the material becomes hydrated. The act of soaking up a fluid is physically different form swelling due to hydration.

Furthermore, the disclosure of the use of carbon to provide a visual marker, as disclosed on Page 2, lines 16-18 in the current application, is not sufficient enough to provide enablement for Claim 59. The disclosure on Page 2, is in the background of the invention describing previous means of visualizing a target area. In lines 18-19 on Page 2, the inventors disclose the drawbacks of using carbon for visualizing a target site, and the remainder of the application teaches away from using carbon as a means of visualizing a target area. Therefore, since the specification teaches away from using carbon as a means of visualizing a target area, the disclosure on Page 2 does not provide enablement for Claim 59.

The claims above remain rejected with the prior art of Foerster et al ('055) due to the disclosure of the claimed subject matter in the above claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BS

MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER